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Joan Claybrook, President

February 25, 2005

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 2004N-0535 (Food and Drug Administration Medical Products Reporting Program)

Dear Madam/Sir:

FDA's MedWatch program is necessary for the proper performance of FDA's functions. Throughout the years of its existence, this program has demonstrated its practical utility by identifying important adverse drug reactions, often unknown at time of approval or unknown as to their extent or sequelae. These findings contributed to revised labeling, boxed warnings (e.g., Lotronex), and discontinuation/withdrawal of drugs (e.g., Trovan, Rezulin, Baycol).

However, the MedWatch program needs to enhance the quality, utility, and clarity of the information to be collected:

The first step in enhancing the quality and utility of Form FDA 3500A is to have FDA vigorously enforce mandatory reporting requirements (e.g., drug manufacturers):

- a. To submit to FDA all postmarketing adverse drug events that are communicated to these mandatory reporters;
- b. To submit these ADR reports to FDA within the required time frames;
- c. To submit, at a minimum, complete information for those ADR fields which a mandatory reporter would have to know, e.g., date the manufacturer received the ADR information and date the manufacturer completed the ADR report;
- d. To improve the completion rate of all fields. For example, in analyses by Public Citizen regarding statins and rhabdomyolysis, only 468 of 936 cases had data sufficient to calculate the time from drug initiation to the onset of symptoms.
- e. To submit ADR reports that are accurate reflections of what the health professional or consumer originally communicated to the mandatory reporter;
- f. To classify ADR reports correctly, e.g., a 15-day "Alert report" is not classified as a Periodic report.

2004N-0535

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Strong enforcement of these steps will help ensure that FDA receives complete, timely, and accurate information.

A second step in enhancing the quality and utility of both the Form FDA 3500A and Form FDA 3500 is to improve data-entry accuracy. For example, there should not be dates in the computerized ADR database that are illogical (e.g., 7200, 2123). Computerized logic checks both during and after data entry are needed. Such logic checks are needed also during completion of the online MedWatch form 3500. Poor quality data means that safety reviewers have to throw out potentially pivotal ADR reports because they are uninterpretable.

In addition to MEDDRA, dictionaries are needed to standardize drug names, NDA numbers, and manufacturer names. Such standardization is necessary for public users to easily group and count within these fields.

A third step in enhancing the utility of both forms is to have the public version of the ADR database posted on the FDA internet site in a timely manner. Tardy database posting subverts the intent of the FOI Act by preventing the public from obtaining current information so it can independently evaluate the links between drugs and adverse events. As recent events have shown, both FDA and the general public are in need of such independent evaluations.

Sincerely,

PL for DK

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